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Customer Number

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Case No.: 59010US002

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First Named Inventor: FLANNIGAN, PAUL J.
Application No.: 10/719959 Confirmation No.: 3577
Filed: November 21, 2003 Examiner: Nihir B. Patel
Title: RESPIRATORY FACEPIECE AND METHOD OF MAKING A FACEPIECE
USING SEPARATE MOLDS

BRIEF ON APPEAL

Mail Stop: Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Appeal Brief is filed in response to the final rejection set forth in the Office Action mailed on December 8, 2005.

Applicants filed a Notice of Appeal on March 8, 2006.

The fee required under 37 CFR § 41.20(b)(2) for filing an appeal brief should be charged to Deposit Account No. 13-3723.

Appellants request the opportunity for a personal appearance before the Board of Appeals to argue the issues of this appeal. The fee for the personal appearance will be timely paid upon receipt of the Examiner's Answer.

REAL PARTY IN INTEREST

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its affiliate 3M Innovative Properties Company of St. Paul, Minnesota.

RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related appeals or interferences.

STATUS OF CLAIMS

Claims 1-23 are pending in this application and are the subject of this appeal.

STATUS OF AMENDMENTS

No amendments have been filed after the final rejection.

SUMMARY OF THE INVENTION

Many respirators that are sold today use a thin rigid structural part to attach filter elements and valves to the respirator mask body. These rigid structural parts are commonly produced through an injection molding process and are often referred to as a "nosepiece" or "rigid insert". A soft compliant material, which is capable of conforming to a person's face, is disposed on or about the rigid structural insert to enable the mask to fit snugly over the wearer's nose and mouth. The use of a rigid insert in conjunction with a soft compliant portion tends to make the mask lighter and more comfortable to wear, particularly when compared to previous masks that had used thick rubber throughout essentially the whole mask body to support the filter cartridges and valves. U.S. Patent 6,016,804 to Gleason et al. shows an example of a mask that uses a rigid insert in conjunction with a compliant face-contacting member:

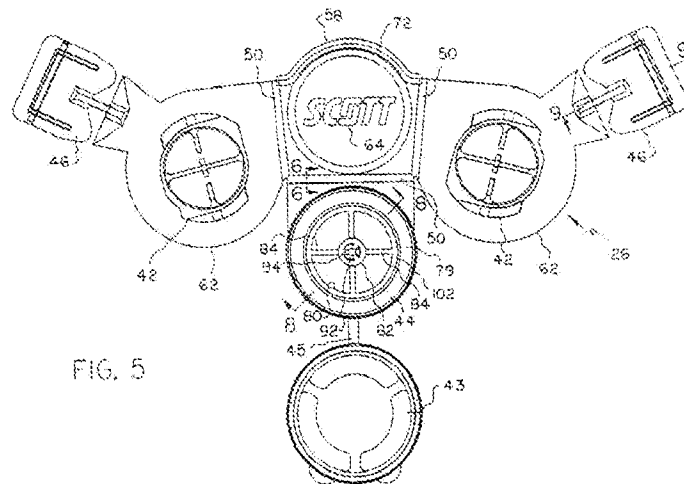


FIG. 5

GLEASON ET AL.

In the above figure, the rigid insert is identified using numeral 26.

The rigid structural components that are employed in mask facepieces regularly incorporate multiple integrated elements that have distinct dimensional tolerance requirements and complex shapes that are customarily formed in molds at relatively great expense. Higher tolerance parts, more-often-than-not, require additional oversight and technical expertise to correctly manufacture. Therefore, for a given material and a given part design, the factor that limits production typically is related to the element that has the greatest tolerance requirement.

To properly utilize the efficiency and accuracy of injection-molding technology, designers have sought to encompass as much detail as possible in the molded part so that the whole rigid structural insert can be manufactured in one step. The result therefore often involves complex tooling that is difficult to maintain and operate, especially when used in remote facilities that do not have access to well-trained technical resources. Thus, the higher tolerance requirements for certain portions of the rigid inserts can limit both the design and the production of the whole insert when made using conventional, single-stage, injection-molded technologies. Additionally, when a change to feature in the facepiece insert is needed, such as a different filter mount, a

whole new mold must be provided to make the change. That is, a separate mold must be furnished for the whole nosepiece and not simply for a portion of it.

Applicants' invention provides a new method of making a facepiece insert, which method comprises: (a) providing a supporting portion of a facepiece insert; (b) providing a fluid communication component separately from the supporting portion; and (c) securing the fluid communication component to the supporting portion to form the facepiece insert.

Applicants' invention also provides a new method of making a respiratory mask body by securing a compliant face-contacting member to the facepiece insert so produced.

The present invention further provides a new facepiece insert that comprises:

- (a) a supporting portion of a facepiece insert; and
- (b) a fluid communication component that is non-integrally joined to the supporting portion.

In applicants' invention, the fluid communication components — which commonly are critical tolerance components because they include more complicated and intricate filter attachment mounts and valve seats — are provided in a first step, and, in another step, a supporting portion of a facepiece insert is joined to the fluid communication component. Applicants FIG. 3 shows the inventive face piece insert 16, which comprises a supporting portion 34 and a fluid communication components 30, 32:

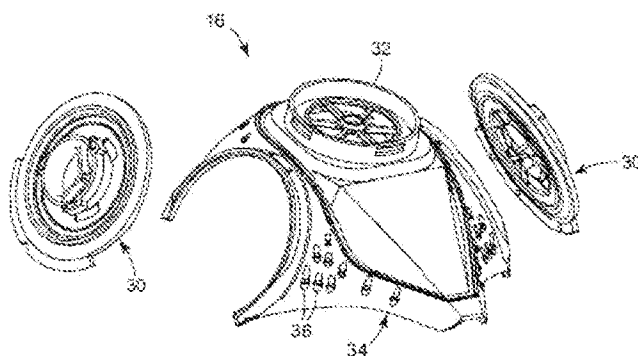


FIG. 3

As shown, the fluid communication components 30, 32 are non-integrally joined to the supporting portion 34.

The facepiece insert and its fluid communication components may be made using, for example, injection molding procedures that are carried out as separate operations. The multi-

stage operation may address the tolerance mismatch between the insert components. Because the supporting part(s) and the fluid communication part(s) of the insert are separately provided, the inventive method can also support a beneficial distributed manufacturing scheme where fluid communication components can be produced in one location, with the associated expertise and equipment, and the final insert assembly can be carried out in a second location, where the expertise and associated equipment are lacking. And if a change to the fluid communication component is needed, for example, to allow for a different type of filter attachment, the whole facepiece insert does not need to be reconfigured in the mold. A separate mold need only be provided for the fluid communication component of the facepiece insert.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

First Ground of Rejection

Claims 1-23 have been rejected under 35 USC § 132, second paragraph, for claiming subject matter that is "new matter".

Second Ground of Rejection

Claims 1-23 have been rejected under 35 USC § 103(a) for being unpatentable over the combined teachings of U.S. Patent 6,016,804 to Gleason et al. (Gleason) in view of U.S. Patent 6,497,232 to Fecteau et al. (Fecteau).

ARGUMENT

First Ground of Rejection

The Examiner's contend that applicants' amendment to the definition "face piece insert" constitutes new matter. The definition and its added matter (in underlined form) is set forth below:

"facepiece insert" means a rigid element(s) that is not a lens of a respiratory mask and is fashioned to form part of the mask body but is made separate from the compliant face contacting member to provide structural integrity to the mask body to allow filtration elements and/or valves to be adequately secured thereto;

The language that is held to constitute new matter therefore refers to "not a lens of a respiratory mask". Applicants assert that support for this definition can be found in the specification, particularly in Figures 1-3. In those Figures, a face piece insert is clearly shown, which insert is not a lens of a respiratory mask. Accordingly, there is clear support for the amended definition.

Although 35 USC § 132 precludes an applicant from adding new matter to an application after filing, the issue pertinent to ascertaining whether new matter is present is not whether new words are added to the specification as filed but whether the concepts expressed by the words are present or illustrated in this specification.¹ Therefore, applicants are entitled to add language to the patent application that can be fairly deduced from the original disclosure.² Because applicants' drawings do indeed show a face piece insert that is not a lens of a respiratory mask, this disclosure is clearly present in the application as filed. Accordingly, the new matter rejection cannot be properly sustained.

Second Ground of Rejection

In the Interview Summary dated February 3, 2006, the Examiners indicated that "[i]f the definition appears not to be new matter, then the claims appear to overcome the current reference and upon further evaluation and/a search will the application for allowance." Thus, the Examiners' position is that the presently-claimed subject matter is allowable, provided no new matter is added to the definition. Since the new matter rejection cannot be properly sustained for the reasons presented above, this rejection is no longer an issue.

To the extent, however, that the new matter rejection cannot be sustained, applicants submit the following argument.

The primary reference to Gleason describes a facepiece insert that is suitable for use with a respiratory mask. As shown in FIG. 4, Gleason's facepiece insert 26 is a single solid part:

¹ *In re Anderson*, 471 F.2d 1237, 1244, 176 USPQ 331, 336 (CCPA 1973) ("The question, as we view it, is not whether "carrying" was a word *used* in the specification as filed but whether there is *support* in the specification for employment of the term in a claim...").

² *Cardinal of Adrian, Inc. v. Peerless Wood Products, Inc.*, 515 F.2d 534, _____, 185 USPQ 712, 716 (6th Circuit 1975); see also *In re Nathan*, 388 F.2d 1005, _____, 140 USPQ 601, 604 (CCPA 1964).

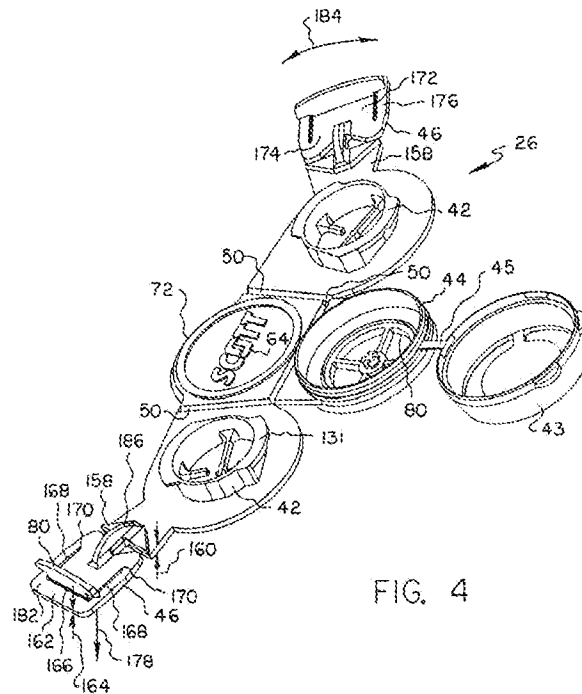


FIG. 4

The fluid communication components 42 and 44 are integrally joined to the supporting portion of the insert 26. Gleason thus, clearly does not recognize the method or respiratory mask of applicants' invention.

The whole thrust of the Fecteau disclosure is to provide a release mechanism for a respirator harness. In FIG. 2, Fecteau shows fluid communication components that are separate from a mask body or facepiece 22:

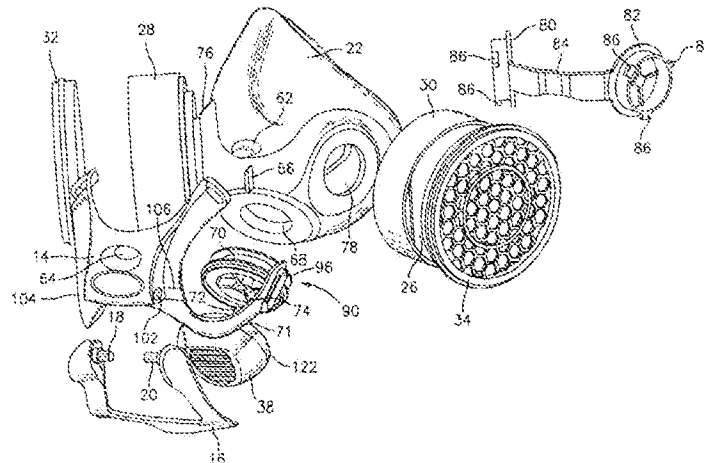


FIG. 2

Fecteau, however, does not describe a facepiece insert. Because Fecteau does not use a rigid insert, the Fecteau mask apparently must use thicker rubber throughout essentially the whole mask body (and therefore would be heavier) to support the filter cartridges and valves.³ Because Fecteau does not describe a rigid insert, it clearly cannot suggest the use of fluid communication components that are separate from the supporting portion of the rigid insert. Only applicants' invention describes a method of making a rigid insert, where the fluid communication component(s) is provided separately from the supporting portion of the insert. Further, only applicants' invention recognizes the benefits that are entailed when the fluid communication component is so provided. As indicated above, when the supporting portion and fluid communication components are made separately, the higher tolerance components can be manufactured in a location where persons are present who have the resources and training to correctly manufacture these parts. Applicants' invention therefore allows less room for error in manufacturing the higher tolerance parts. Applicants' invention also is more versatile than prior manufacturing techniques. A whole new mold does not need to be provided when a different filter mount is decided to be employed. If a different filter cartridge is desired to be used on the same facepiece, the manufacturer does not have to fashion a whole new mold for the article.

In the Amendment mailed April 27, 2005, and in an Amendment mailed July 15, 2004, applicants provided amended definitions for the terms "compliant faced contacting member", "face piece insert", and "mask body". Those terms, in amended form, are reproduced below for ease of reference:

"compliant face contacting member" means the portion of a mask body that engages the facepiece insert directly or otherwise and is compliantly fashioned for making contact with a person's face to allow the mask body to be comfortably supported over a person's nose and mouth.

"facepiece insert" means a rigid element(s) that is fashioned to form part of the mask body but is made separate from the compliant face contacting member to provide structural integrity to the mask body to allow filtration elements and/or valves to be adequately secured thereto.

³ Please see applicants' specification on page 1, lines 15-20, which describes the thicker rubber facepieces that had been used prior to the invention of rigid inserts by Burns et al. — see U.S. Patent 5,062,421.

"mask body" means a structure that can fit over the nose and mouth of a person and that can help define an interior gas space separated from an exterior gas space.

As indicated above, the references to Gleason and Fecteau do not teach or suggest the present invention because they do not teach or suggest a face piece insert that has separate fluid communication components. In Gleason, the fluid communication components 42, 44 are integral parts of the face piece insert 26. In Fecteau, the respirator 10 has a face piece 22 that does not comprise a face piece insert. In Fecteau, the fluid communication components 70 and 80, 82 are illustrated as being parts separate from the face piece 22 but not from a face piece insert. Thus, neither Gleason nor Fecteau teach or suggest providing a fluid communication component separately from the supporting portion of a face piece insert. Further, only applicants' invention recognizes the benefits that are entailed when the fluid communication component is provided separately from the supporting portion of the insert. When these parts are made separately, the higher tolerance components can be manufactured in a location where persons are present who have the resources and training to correctly manufacture these parts. The present invention therefore, allows less room for error in manufacturing the higher tolerance parts and is more versatile than known manufacturing techniques. Additionally, a whole new mold does not need to be used when a different filter mount is used in the face piece insert. Therefore, if a different filter cartridge is desired to be used on this same face piece, the manufacturer does not have to fashion a whole new mold for the insert. The manufacturer only needs to make a new mold for the fluid communication component.

Because Gleason and Fecteau fail to teach or suggest the basic elements of applicants' invention and also fail to recognize the benefits that are provided by the invention, these references, whether taken alone or in combination, would not have rendered applicants' invention obvious to a person of ordinary skill within the meaning of 35 USC § 103.

CONCLUSION

For the foregoing reasons, appellants respectfully submit that the Examiner has erred in rejecting this application for including new matter and for being obvious over the prior art. Please reverse the decision below.

Respectfully submitted,

May 1, 2006

Date

By:

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CLAIMS APPENDIX

1. (original) A method of making a facepiece insert that has at least one fluid communication component, which method comprises:
 - (a) providing at least one supporting portion of a facepiece insert;
 - (b) providing at least one fluid communication component separately from the supporting portion of the facepiece insert; and
 - (c) securing the at least one fluid communication component to the at least one supporting portion.
2. (original) A method of making a respiratory mask body, which method comprises the steps of claim 1 and further comprises:
 - (d) securing a compliant face-contacting member to the facepiece insert.
3. (original) A method of making a respiratory mask, which method comprises the steps of claim 2 and further comprises:
 - (e) securing a harness to the mask body.
4. (original) The method of claim 3, further comprising providing at least one filter cartridge that is capable of being attached to the at least one fluid communication component.
5. (original) The method of claim 1, wherein the at least one fluid communication component is a critical tolerance component.
6. (original) The method of claim 2, wherein the at least one fluid communication component is a critical tolerance component.
7. (original) The method of claim 3, wherein the at least one fluid communication component is a critical tolerance component.
8. (original) The method of claim 1, wherein the at least one supporting portion of the facepiece insert and the at least one fluid communication component are made from similar polymeric materials and are fused together.

9. (original) The method of claim 1, wherein the at least one fluid communication component has a tolerance of less than 0.15 millimeters.

10. (original) The method of claim 1, wherein the at least one fluid communication component has a tolerance of less than 0.1 millimeters.

11. (original) The method of claim 1, wherein the at least one fluid communication component has a tolerance of less than 0.05 millimeters.

12. (original) The method of claim 1, wherein the supporting portion of the facepiece insert has a tolerance of about 0.16 to 0.3.

13. (original) A facepiece insert that comprises:
(a) a supporting portion; and
(b) a fluid communication component that is non-integrally joined to the supporting portion.

14. (original) A respiratory mask body that comprises the facepiece insert of claim 13, and further comprises a compliant face contacting member that is non-integrally joined to the supporting portion of the facepiece insert.

15. (original) The respiratory mask body of claim 14, wherein the fluid communication component has a tolerance of 0.15 or less, and wherein the supporting portion has a tolerance of about 0.16 mm or greater.

16. (original) A respiratory mask, that comprises the mask body of claim 14, and further includes a harness for supporting the mask body over a person's nose and mouth.

17. (original) A respiratory mask, that comprises the mask body of claim 14, and further includes a filter cartridge for supporting the mask body over a person's nose and mouth.

18. (original) The respiratory mask of claim 16, wherein the fluid communication component comprises part of an inhalation valve.

19. (original) The respiratory mask of claim 16, wherein the fluid communication component comprises part of an exhalation valve.

20. (original) A respiratory mask of claim 16, wherein the fluid communication component has a tolerance of 0.15 or less, and wherein the supporting portion has a tolerance of about 0.16 to 0.3 mm.

21. (original) The respiratory mask of claim 16, wherein the supporting portion and the fluid communication component are fused together.

22. (original) A respiratory mask that comprises:

(A) a mask body that includes:

(1) a facepiece insert that includes:

(a) a supporting portion;

(b) at least one fluid communication component that is non-integrally joined to the supporting portion and that is a critical tolerance component; and

(2) a compliant face-contacting member that is non-integrally joined to the supporting portion of the facepiece insert; and

(B) a harness for supporting the mask body at least over a person's nose and mouth.

23. (original) The respiratory mask of claim 23, further comprising at least one filter cartridge that is secured to the mask body at a location where the fluid communication component resides.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.